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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,030	03/09/2000	James A Thomson	96-0296-96544	4331

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/522,030	THOMSON, JAMES A	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-13 and 17* is/are allowed.

6)☒ Claim(s) *14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is an original application filed March 9, 2000.

Applicant's amendment filed October 25, 2004, has been received and entered. Claims 1, 7, 13, 14 and 17 have been amended. Claims 15 and 16 have been cancelled. Claims 1-14, and 17 are pending and currently under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 17 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-18 of copending Application No. 10/430497 (US Patent application 20030190748). Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn generally to a method of culturing human embryonic stem cells in serum free conditions wherein the medium is supplemented with FGF.

Applicants comments that 10/430,497 is a later filed co-pending application is noted (see page 5 of Applicant's amendment). However, at this point the instant application is not in condition for allowance, therefore the rejection is maintained for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 rejected because there is insufficient antecedent basis is withdrawn.

The amendment to the claim as suggested in the previous office action has obviated the basis of the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.* ('372), Hogan *et al.* ('926) and Goldsborough *et al.* (FOCUS 20(1):8-12, 1998).

Applicants argue that the claims have been amended to more clearly set forth the invention in the claimed method and to further recite the unexpected result of practicing this method. See Applicants amendment, bottom of page 5. Applicants arguments have been fully considered and found persuasive in part.

With respect to claims 1-13 and 17, Examiner agrees that the amendments have differentiated the claimed invention from that taught by the combination of Hogan *et al.* ('372 and '926) and Goldsborough *et al.* More specifically, the claims have been amended to more clearly set forth the method and set forth unexpected affects of culturing primate stem cells under the recited conditions. The rejection over these claims is withdrawn.

With respect to the product claim of claim 14, the amendment is noted, however the limitations of intended use and description of the properties of FGF do not materially alter the structural properties of the product claimed. Unlike the method claims that require that practicing the method provides the conditions to maintain primate embryonic stem cells in a undifferentiated and proliferative state, the product claim can be used for any intended use and encompasses any consequence of culturing. As noted previously, Examiner acknowledges that the evidence in the instant specification provides support for an unexpected effect in methods of any form of FGF in culturing primate cells with a serum supplement for providing the specific serum free conditions, however claim 14 recites the open language of "comprising" and only sets forth an intended use of the claimed composition. The combined teachings of Hogan *et al.* ('372), Hogan *et al.* ('926) and Goldsborough *et al.* Therefore, because of the breadth of claim 14, and the ability to use the claimed composition to intended ends that are different from that set forth in the claim, it is maintained that the claimed product would be obvious over the teachings

of Hogan *et al.* and Goldsborough *et al.* Given the breadth of the instantly claimed product, there was a reasonable teaching and expectation that the addition of growth factors, in particular the family of FGFs would be necessary in the optimization of growth conditions for embryonic stem cells, and that the addition of these factors would result in better culturing conditions.

Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

Claims 1-13 and 17 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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